UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/231,565	04/22/94	KAWAKAMI Y	20264124

18N1/0703

WILLIAM S. FEILER, ESQ.
MORGAN & FINNEGAN
345 PARK AVENUE
NEW YORK, NEW YORK 10154

HUFF, S EXAMINER	
ART UNIT	PAPER NUMBER
1806	11

DATE MAILED: 07/03/96

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Office Action Summary	Application No. 08/231,565	Applicant(s) Kawakami et al
	Examiner Sheela J. Huff	Group Art Unit 1806

☒ Responsive to communication(s) filed on *Nov 2, 1995* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire ~~three (3) month(s), or~~ thirty days, ~~whichever is longer,~~ from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-57* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-57* are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Part III DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-5, drawn to the nucleic acid sequence of MART-1, classified in Class 536, subclass 23.1+.

Group II. Claims 6-19, 38-40 and 46-48, drawn to the protein MART-1 and methods of making and using MART-1, classified in Class 514, subclass 12+ and Class 530, subclass 328 and 350+.

Group III. Claims 20-22 and 28-35, drawn to antibodies and methods of using said antibodies, classified in Class 530, subclass 387.7 and Class 435, subclass 7.23.

Group IV. Claims 41-43, drawn to peptides of gp100, classified in Class 530, subclass 328.

Group V. Claims 51-52, drawn to a method of identifying genes, classified in Class 435, subclass 6.

Group VI. Claims 53-55, drawn to method of assessing the immunogenity of peptides or MART-1 or gp100, classified in Class 435, subclass 29.

Group VII. Claims 23-27 and 36-37, drawn to methods for detecting mRNA or the genomic nucleic sequence, classified in Class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I-VII are disclosed as different combinations which are not connected in design, operation or effect. These combinations are independent if it can be shown that (1) they are not disclosed as capable of use together, (2) they have different modes of operation, (3) they have different functions, or (4) they have different effects. (MPEP 806.04, MPEP 808.01). In the instant case the combinations are unrelated in chemical composition and structure, in physicochemical properties and in function.

Specifically, the nucleic acid sequence of Invention I can be used to synthesize a protein whereas the antibody of Invention III or the proteins or peptides of Inventions II or IV cannot. The antibody of Invention III can be used to produce an immunogen for making anti-idiotype antibodies whereas the nucleic acid sequence of Invention I cannot. The proteins and peptides of Invention II and IV can be also be used as an immunogen where as the nucleic acid sequence of Invention I cannot. The protein and peptides of Invention II and IV are different amino acid sequences and therefore are chemically and structurally different. Similarly, the antibody of Invention III and the proteins or Inventions II or IV are also chemically and

structurally different products. Thus, the products of Inventions I-IV are separate and patentably distinct from each other.

The methods of Inventions II-III and V-VII are separate and patentably distinct from each other for the following reasons. The methods of Invention II involving making MART-1 by recombinant methods and using MART-1 to prevent or treat melanomas whereas the methods of Inventions III and V-VII do not involve making MART-1 or administering it to a patient. Thus, the considerations and issues involved in the methods of Invention II are considerable different from the issues of Invention III. The methods of Invention III are distinct from the methods of Inventions V-VII because the methods of Invention involve using antibodies to detect the presence of MART-1 protein whereas the methods of Inventions V-VII involve using nucleic acid probes (invention VII) or creating cDNA libraries (Invention V) or peptide libraries (Invention VI). The methods of Inventions V-VII are distinct because the involve different steps and reagents--invention V involves creating cDNA libraries, invention VI involves peptide libraries and invention VII involves nucleic acid probes. Thus, the methods of Inventions II-III and V-VII are separate and patentably distinct from each other.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by

their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and the search required for Invention I is not required for Inventions II-VII, the search required for Invention II is not required for Inventions I and III-VII, the search required for Invention III is not required for Inventions I-II and IV-VII, the search required for Invention IV is not required for Inventions I-III and VI-VII, the search required for Invention V is not required for Inventions I-IV and VI and the search required for Invention VI is not required for Inventions I-V and VII restriction for examination purposes as indicated is proper.

Election of Species

5. This application contains claims directed to the following patentably distinct species of the claimed invention:

a. If applicant elects either Group II or Group IV, then applicant should elect either MART-1 or gp100 of claims 44-45 and 49-50. For example, if applicant elects Group II, then claims 44-45 (referring to MART-1) and 49-50 (referring to MART-1) will be examined with Group II.

b. If applicant elects Group I, then claims 56-57 are subject to election. If applicant elects the sequence of MART-1, then claims 56-57 will be examined with Group I. However, if

applicant elects the sequence of gp100, the sequence will be examined alone.

c. If applicant elects Group VI, then applicant should elect either MART-1 or gp100.

As explained above, MART-1 and gp100 are distinct proteins encoded by distinct nucleic acid sequences and thus are chemically and structurally unrelated.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, either claims 1-5, claims 6-19, 38-40, 46-48, claims 41-43 or claims 53-55 are generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

6. No attempt was made to call the attorney of record to request an oral election to the above restriction requirement because of the complexity of the restriction.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is (703) 305-7866. The examiner can normally be reached on Monday-Thursday from 6:30am to 3:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marian Knode, can be reached on (703) 308-4311. The FAX phone number for this Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Sheela J. Huff
6/28/96

Sheela J. Huff
Patent Examiner
Group 1800